510(K) SUMMARY

APR 23 2014

510(k) Owner: Xlumena, Inc.
453 Ravendale Drive, Suite H
Mountain View, California 94043
Phone: (650) 961-9900

Contact: Jane Beggs
Fax: (650) 961-9900

Date Prepared: 04 March 2014

Proprietary Name: AXIOS™ Stent and Delivery System

Common Name: Pancreatic drainage stent and delivery system
Regulation: 21 CFR 876.5015
Regulation Name: Pancreatic drainage stent and accessories
Regulatory Class: II
Product Code: PCU

Predicate Device: AXIOS™ Stent and Delivery System (K123250)

Device Description: The AXIOS™ Stent and Delivery System is an endoscopic device designed to deliver a fully-covered stent between a pancreatic pseudocyst and the gastrointestinal tract.

The AXIOS™ Stent is a flexible, MR compatible, fully-covered self-expanding Nitinol stent preloaded within the AXIOS Delivery System.

The AXIOS™ Delivery System is compatible with endoscopes equipped with a 3.7mm diameter or larger working channel. The AXIOS Stent and Delivery System is provided sterile, disposable and intended for use during a single patient procedure.

The AXIOS Stent and Delivery System are sterilized by a validated method of sterilization via Ethylene Oxide (EO). The validation was conducted in accordance with recognized consensus standards.

Indications for Use: The AXIOS™ Stent and Delivery System is indicated for use to facilitate transenteric endoscopic drainage of symptomatic pancreatic pseudocysts ≥ 6cm in size, with ≥ 70% fluid content that are adherent to the gastric or bowel wall. Once placed, the AXIOS Stent functions as an access port allowing passage of standard and therapeutic endoscopes to facilitate debridement, irrigation and cystoscopy. The stent is intended for implantation up to 60 days and should be removed upon confirmation of pseudocyst resolution.

Principles of Operation: The AXIOS Delivery System is placed into the stomach through an endoscope that is passed through the patient's mouth and into an area of the stomach adjacent to the target pseudocyst. After creating a small opening in the wall of the stomach and a small opening in the pseudocyst, the physician positions the compressed stent across both openings, releases the stent and removes the delivery system. Once expanded, the stent allows the contents of the pseudocyst to drain into the stomach. When the pseudocyst has drained and decreased in size, the physician can use standard endoscopic tools to remove the AXIOS Stent.

Summary of Technological Characteristics: Comparison of materials used in the manufacture of the predicate and subject devices notes that the optional hydrophilic coating to be the only difference. The design and other technological characteristics are the same. No change was made to the AXIOS stent.

Determination of Substantial Equivalence: Substantial equivalence is supported through comparison with the predicate device: The AXIOS Stent and Delivery System. The subject device has the same intended use, utilizes the same principles of operations and fundamental scientific technology as that of the predicate device. No change was made to the AXIOS stent.

Non-clinical testing included biocompatibility testing, which was conducted in accordance with the FDA guidance entitled, "Required Biocompatibility Training and Toxicology Profiles for Evaluation of Medical Devices," dated May 1, 1995 (G95-1); as well as an comparison of tracking force with the predicate device.

Non-clinical testing confirmed the modified AXIOS Stent and Delivery Catheter is biocompatible, non-toxic and safe for temporary implantation. Bench testing of device function verified that the device meets product specifications, performance characteristics and requirements established by special controls for a pancreatic drainage stent and accessories.

Conclusions Drawn from Testing: Test results established that the specified performance levels were achieved and mitigations for anticipated risks were met through standard test methods, available guidances and recognized technical requirements. In conclusion, the modified device is as safe, as effective and performs as well as or better than the predicate AXIOS Stent and Delivery System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 23, 2014

Xlumena, Inc.
Jane Beggs
VP, Regulatory and Clinical Affairs
453 Ravendale Drive, Suite H
Mountain View, CA 94043

Re: K140561
Trade/Device Name: AXIOS™ Stent and Delivery System
Regulation Number: 21 CFR§ 876.5015
Regulation Name: Pancreatic drainage stent and delivery system
Regulatory Class: II
Product Code: PCU
Dated: March 21, 2014
Received: March 24, 2014

Dear Jane Beggs,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner -S

for
Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

7 INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K140561

Device Name:

AXIOS™ Stent and Delivery System

Indications for Use:

The Xlumena AXIOS™ Stent and Delivery System is indicated for use to facilitate transgastric or transduodenal endoscopic drainage of symptomatic pancreatic pseudocysts ≥ 6cm in size, with ≥ 70% fluid content that are adherent to the gastric or bowel wall. Once placed, the AXIOS Stent functions as an access port allowing passage of standard and therapeutic endoscopes to facilitate debridement, irrigation and cystoscopy. The stent is intended for implantation up to 60 days and should be removed upon confirmation of pseudocyst resolution.

Prescription Use _X_ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Herbert P. Lerner -S
2014.04.23 12:30:31 -04'00'